

EXHIBIT BB

ETHICON, INC.

Pelvic Floor Repair

MAR 31 2003

Extended Review of Medical Literature

R&D - CENTRAL FILE

May, 2001

Pelvic prolapse describes a varied and complex array of support structure failures. The response to these failures is an even more complex array of surgical interventions.

Objective

This document was prepared as an expansion and update of the original literature review prepared by Brigitte Hellhammer, MD in June 2000 and entitled *Meshes in Pelvic Floor Repair*. This document derives from the literature further detail regarding the surgical interventions used in the treatment of pelvic prolapse. This review examines the materials used and results reported with their use, particularly focusing on any issues associated with the material chosen. The combined literature reviews will help determine whether further evidence is needed in order to support the use of mesh materials in pelvic floor reconstruction.

Procedure

In June, 2000, the ETHICON, Inc. Scientific Information Service (SIS) prepared a comprehensive bibliography of the literature on the topic of materials, particularly meshes, used for gynecologic surgery. A physician trained in Obstetrics and Gynecology, who serves as a consultant to the organization, identified the articles from the bibliography that were most pertinent to this review. An additional search of subsequent literature (June 2000 – April 2001) on Pelvic Floor Repair was performed using Index Medicus. Relevant articles were added to the bibliography for this review.

Discussion

The review subset included 23 original and 5 review articles describing procedures that could be described as pelvic floor repair. The conditions addressed by the intervention were used as the first data classification:

- Cystocele (anterior vaginal wall)
- Rectocele (posterior vaginal wall)
- Combined defects

Surgical approach was used as the second classification:

- Vaginal
- Laparoscopic
- Abdominal
- Combined/other

Additional article identifiers included location of author (US or Europe) and mesh application (suspension, patch or both; none where mesh was not used). A table of information extracted from the original is included in Appendix A.

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Original Articles

Cystocele Repair

Approach	Vaginal
No. of articles	3
Total Subject count	137
Follow-up range (mos)	21-24
Materials used	Polypropylene mesh Polyester/pga mixed fiber mesh
Comments	All Grade 4 or recurrent No material problems described

Three articles were identified that focused on cystocele repair and all reported a vaginal approach.. Cystocele repair is also often a component of the combined defect repair and is described below.

All patients included in these reports were diagnosed with Grade 4 cystocele or recurrent cystocele.

Among the 137 cases, no instances of mesh erosion or other material-implicated complications were described. Safir(18) frequently included other transvaginal repairs when repairing the Grade 4 cystoceles. His repair technique relies on connective tissue replacement of a temporary scaffold provided by a fully absorbable mesh and reported 92% of the patients with excellent objective and subjective results for the cystocele repair. Migliari (14) advocates the use of mesh for this intervention, expressing concerns about relying on demonstrably weakened tissue to provide the needed support.

Rectocele Repair

Approach	Vaginal & Perineal	Perineal
No. of articles	1	2
Total Subject count	10	13
Follow-up range (mos)	?	14-29
Materials used	PGA suture PGA mesh	Polypropylene mesh
Comments	3 granuloma removed Improvement in coital comfort when mesh was used	No problems with material reported

Catelo-Branco (4) reported a very small, randomized series comparing plication with absorbable mesh. He rejected the use of permanent mesh fearing rejection followed by recurrence. The use of mesh reduced the loss of vaginal mucosa that presumably explained the difference (40% vs 0%) in

coital problems in the mesh group. Three cases required one-time removal of granulation tissue ("granulamata"), 2 in the mesh group, 1 in the plication group. Parker (17) acknowledges the potential for infection when permanent mesh is used but feels the scarring that follows mesh removal would adequately reinforce the rectovaginal septum.

Enterocèle Repair

Approach	Laparoscopic
No. of articles	1
Total Subject count	3
Follow-up range (mos)	10.5
Materials used	PGA suture

The only article identified describing isolated enterocèle repair described a laparoscopic technique. The limited literature is expected as enterocèle frequently occurs with other pelvic floor problems and enterocèle repair is included in the defined defects repair section.

Combined Defects Repair

Approach	Vaginal	Laparoscopic	Abdominal
No. of articles	7*	1	9*
Total Subject count	620	2	522
Follow-up range (mos)	11 – 36	12	3 – 32
Materials used	Suture chromic absorbable & non-abs braided non-abs monofil non abs Polypropylene mesh (2) PTFE mesh (sling) Autologous tissue (sling)	Polypropylene mesh	Suture monofilament, abs & non PTFE Mesh (3) Polyester Mesh(3) Polypropylene Mesh(3)
Comments	One reported mesh erosion, vaginal wall	No reported product problem	1 mesh infection reported Mesh erosion reported, typically infrequent, high with some techniques

*Article 2, randomized comparison of vaginal and abdominal approach, is included twice

The largest article grouping of this series is the most varied. Although most of the procedures described include a vaginal vault suspension, the approach, site of attachment and materials used vary greatly. These procedures address the most severe cases of vaginal prolapse, simultaneously correcting several defects.

Vaginal Approach

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Julian (11) studied the use of polypropylene mesh applied in the area under the anterior vaginal wall segment created after anterior colporrhaphy, paravaginal repair and urethral suspension by evenly dividing a group of 24 revision patients with and without mesh. Recurrent prolapse at two-year follow-up was observed in 4/12 of the patients treated without mesh, none were observed in the mesh treatment group. Mesh problems occurred in 3/12 patients; granulation tissue causing spotting in one patient, mesh erosion in one patient and perforating mesh fibers in one case.

Meeks (13) describes a complex procedure to repair cystocele, urethrocele, rectocele, enterocele and the perineal body in a single procedure that averages 163 minutes in his series. He omits any comments about mesh but explains the choice of absorbable suture to possibly enhance local fibrosis and improve fixation. Nicita (16) uses a large piece of polypropylene to replace the reduced function of the levator ani muscle. In his series of 44 patients, he reported one incident of vaginal wall erosion, the size of a quarter, which was removed at an outpatient visit. He attributes the lack of infections possibly to the open fabric of the mesh. He further comments that reexploration, not yet attempted, and may be difficult because of fibrosis. Shull(20) acknowledged the challenge of managing the anterior compartment but continues to use only nonabsorbable braided suture for reconstruction. His concern about placing a nonabsorbable foreign body in a clean-contaminated wound leads to a refusal to consider synthetic graft materials.

Abdominal approach

Fox (10) described a procedure that added mesh interposition to suspension for patients with a rectocele and vault prolapse; the procedure used a single piece of Teflon mesh. She reported a single case of mesh infection (time to event not reported) which required mesh removal.

Kohili(12) described a 12% erosion rate following abdominal sacrocolpopexy. Because two of the erosion events involved exposure of suture rather than mesh, the mesh erosion rate (5/57) was 9%. The mesh erosion was in the vaginal apex in all cases and appeared, on average, 14 months after the procedure. No characteristics predictive of erosion were identified. The author reported change to cadaveric *fascia lata* as the suspensory graft material.

Visco (21) describes a combined abdominal and vaginal colpopерineopexy when posterior vaginal fascia is severely attenuated. He reported an overall erosion rate of 5.5% (including abdominal and combined approaches) but observed a far higher rate (16 to 40%) in those procedures involving combined approaches. Median time to erosion event ranged from 15.6 months for the abdominal procedures to 4.1 months for the combined procedures that included vaginal mesh placement. No predictors of mesh erosion beyond surgical approach were identified. The author suggests that mesh erosion may be a manifestation of bacterial contamination, noting consistency with the increased rate of erosion noted with the vaginal approach.

Review Articles

Five review articles are also included in the bibliography. The articles either focus on experiences pelvic floor reconstruction technique (R3, R4 and R4) or summarize the use of mesh in gynecologic surgery (R1 and R2).

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Summary

Mesh is used successfully in the major procedures for treatment of pelvic wall or pelvic floor prolapse. Theoretical advantages for mesh use have been described, depending on the mesh application. The two major reasons for using mesh are:

Patch to reduce the need to tighten tissues where support structures are weakened (cystocele repair)

- + reduction in recurrence
- + retention of vaginal size to reduce dyspareunia
- infection intractable when mesh is present
- mesh may lose vaginal tissue covering (erosion)

A substitute for autologous or cadaveric tissue for replacement support and interposition (e.g. sacrocolpopexy)

- + no harvesting of autologous tissue
- + no use of banked tissue
- + material of known strength properties, especially important as autologous tissues in afflicted patients are suspect
- infection intractable when mesh is present
- mesh may lose vaginal tissue covering (erosion)

Mesh products of different fibers and construction have been used for both types of applications:

Mesh	Ref. No Patch	Ref. No. Support structure
Polypropylene	14,17,22	8,11,12,16
Polyester		7,12,21
Polyglycolide	4,18	
PTFE or expanded PTFE		5,6,10,21
Mixed fiber (polyglycolide and polyester)	15	9

Conclusion and Recommendation

There appears to be a good amount of evidence in the surgical literature documenting the use of mesh for the repair of pelvic floor defects. Pelvic floor problems are not often isolated and, as expected, the approach to their treatment is often individualized. The literature reflects a variety of applications for the use of mesh utilizing the gamut of available materials. Consistent throughout the articles reviewed

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is the lack of reported serious complications resulting from the mesh products leading us to believe that the use of mesh in pelvic floor repair is safe.

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Appendix A

Table of Articles Reviewed

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Cystocele

Approach	Ref	Yr Start	Procedure Description	Material used	No. of patients	Follow (mo)	Recurrence %	Material infection	Comments
Vaginal									
	14 E I	1997	Anterior colporrhaphy; prox Sutures at level of bladder neck, distal level of vaginal cuff TVT used if stress incontinence dx Enterocle repair if needed	Polypropylene mesh fixed pga suture	12	20.5	NR 75% cured'	None	All patients recurrent vaginal bulging preop Included TVT as part of intervention
	15 E I	NR	Four corner fixation of mesh	Mixed fiber mesh (60% pga & 40% polyester) fixed with polypropylene suture GII titanium anchors to pubis in 5 patients	15	23.4	7 + 2 cases of new onset enterocele @6 mos postop	None	Grade IV cystocele Broad spectrum IV ab 24 hrs after procedure followed by cephalosporin Foley catheter retained for 7 days
	18 U I	NR	4 defect repair Hysterectomy if utine prolapse Culdoplasty Enterocle repair	Pga mesh for enterocele repair and culdoplasty Polyglactin suture for suspension Crumpled pga mesh, positioned beneath bladder base Pga suture for midline cystocele	130	21	8	None	Grade IV cystocele preop Although multiple repairs were performed on most patients, article focus and results discussion is on the cystocele repair.
Laparoscopic	-	-	-	-	-	-	-	-	-
Abdominal	-	-	-	-	-	-	-	-	-

Rectocele

Approach	Ref *	Yr Start	Procedure Description	Material used	No. of patients	Follow (mo)	Recurrence %	Material reaction	Comments
Vaginal	4 E I	1996	Suture: Passed interrupted suture margins of levator ani; excess posterior vaginal mucosa excised and tied down Mesh: fixed over margin of rectocele with interrupted suture, no removal of vaginal tissue	Suture: polyglycolic acid Mesh: polyglycolic acid fixed with pga suture	Suture: 5 Mesh: 5	12	Suture: 0 Mesh: 0	Posterior wall granuloma Suture: 1 Mesh: 2	Procedure included additional perineal incision Randomized comparing absorbable mesh and absorbable suture
Laparoscopic	-								
Abdominal	-								
Perineal	17 E I	NR	Perineal approach	MARLEX mesh	4	14	None 3 of 4 success, 1 improved	NR	
	22 E I	NR	Perineal approach	MARLEX mesh	9	29	NR	NR	

Enterocèle

Approach	Ref *	Yr Start	Procedure Description	Material used	No. of patients	Follow (mo)	Recurrence %	Material reaction	Comments
Laparoscopic									
	3 U NM	NR	Modified Moschowitz technique	Polyglactin suture	3	10.5	0	NR	

Combined Defects

Approach	Ref *	Yr Start	Procedure Description	Material used	No. of patients	Follow (mo)	Recurrence %	Material reaction	Comments
Vaginal									
	5 U B	1997	Autologous: free vaginal wall graft PTFE; patch 3.5x1.5cm Sling centered under bladder neck	Autologous tissue or PTFE (antimicrobial) Both used PTFE suture	Tissue:20 Mesh: 20	22	NR (incontinent e reported, unclear reference to cystocele recurrence)	None	Primary interest is sling, most patients had additional pelvic floor repairs Randomized comparing autologous vaginal wall sling and mesh All patients had UI in addition to vaginal prolapse
	13 U NM	1981	Suspension of vagina to iliooccyeus (prespinous fascia) Posterior colporrhaphy Perineal body repair	Chromic suture	110	36	NR	75% had enterocele with associated cystocele, urethrocele, rectocele or perineal body defect 82% showed cystocele 81% had rectocele	
	16 E I	1996	Large mesh placement	Polypropylene mesh fixed with PROLENE suture	44	13.9	Partial (to first degree) 3/6 with third degree uterine prolapse	Erosion 1 subject	'Erosion provoked by a mesh could occur beyond one year'
	19 U NM	1988	Sutures placed with 3 points of penetration – white line, pubocervical fascia and epithelium Abandoned suspension repair as unnecessary	Nonabsorbable suture and absorbable suture	62	19.2	NR	98% coexisting localized pelvic support defects anterior 100% support defects other pelvic sites 69% previous pelvic surgery	
	20 U NM	NR	Suspension Side-side plication	Nonabsorbable braided suture	302	N=13 (evaluable) + 5 of total	NR	Refrained from synthetic graft concern about nonabsorbable foreign body in clean-contaminated wound	

Approach	Ref *	Yr Start	Procedure Description	Material used	No. of patients	Follow (mo)	Recurrence %	Material reaction	Comments
	23 U I	NR	Abdominal sacral colpopexy Abdominal enterocoe repair Paravaginal repair Culoplasty	MARLEX mesh ETHIBOND or PROLENE	20	11.3	Vault prolapse 0 Enterocoe 0 Cystocele N= 3	None	
Laparoscopic									
pic	9 E S	NR	Mesh attachment between vaginal walls and uterus and iliac laparoscopic Burch posterior colpopereineorrhaphy	VICRYL composite mesh (2 pieces)(with polyester) anchored with permanent polyester suture	2	12	0	NR	Amoxicilline and clavulanic acid IV for 2 days, then 10 days oral
Abdominal	1 U NM	NR	Hysterectomy if uterine prolapse Uteroscalar ligament vaginal vault suspension Culoplasty to obliterate cul-de-sac or posterior enterocoe Other reconstruction as required	Monofilament suture, both absorbable and non-absorbable	46	15.5	10	NR	
	6 E I	NR	Hysterectomy followed by sacropexy or colpolystero-sacropexy preserving uterus Also some with culoplasty and anterior colposuspension	PTFE mesh	21	31.6	29% cystocele	NR	
	7 U S	1995	Abdominal sacral colpopexy culoplasty	MERSELENE mesh, double thickness	19	3	0 Correction was complete in 63%	NR	A report of modified procedure used for 19 of the 97 patients who underwent surgery for pelvic prolapse during 1 yr

Approach	Ref *	Yr Start	Procedure Description	Material used	No. of patients	Follow (mo)	Recurrence %	Material reaction	Comments
	8 E	1994	Abdominal sacral colpopexy (ASC) Halban culdoplasty, all cases Burch colposuspension, 6 cases	PROLENE Mesh fixed with delayed absorbable sutures on vaginal apex and permanent suture to anterior-sacral fascia	15	20	0	None	Irrigate with vancomycin followed by 4 days parenterally
	10 E B	NR	Scrocolpopexy Cystocele repair, if present	Teflon mesh attached with polyester suture Second mesh for cystocele repair (3 cases)	29	14	10	1 mesh infection	
	11 U I	1989	Anterior colporrhaphy paravaginal repair urethral suspension Treatment grp included anterior vaginal segment reinforced sewed from urethrovagicle junction to vaginal apex and junction of obturator and levator fascia	MARLEX polypropylene mesh	12 Treatment 12 control	24	Control: 33 Treat: 0	1 erosion 1 granulation tissue 1 perforating mesh fibers	Controlled comparison with and without mesh Procedure recommended after two or more prior operative failures
	12 U S	NR	Sacrocolpopexy Moschowitz culdeplasty	Double thickness synthetic mesh MARLEX 47 cases MERSILENE 10 cases fixed with ETHIBOND secured from vaginal apex along posterior vaginal wall	57	19.9	NR	Erosion 12 % (mesh and suture, 9% mesh only) occurrence mean 14.0 mos after procedure (4-24 mos) Suture erosion post prox vaginal N=2, responded to cons therapy Mesh erosion at vaginal apex N = 5; required addnl surgery	Retrospective chart review 8-year period Mesh excision with vaginal advancement cured erosion with no recurrence of vault decentus No obvious predictors. Abandoned use of synthetic graft

Approach	Ref *	Yr Start	Procedure Description	Material used	No. of patients	Follow (mo)	Recurrence %	Material reaction	Comments
Sacral colpopexy – 155 sacral colperineopexies – 88 combined abd-vaginal procs – 30	21 U S	1992	MERSILENE mesh in all but 4 patients (received GORETEX) Fixed by various monofilament and braided permanent suture	2/3	12.3	NR	Erosion 5.5% Significantly higher rates with combined procedures (16 and 40%) Time to erosion appearance 15.6 mos; 4.1 mos with vaginal mesh	Used a combined abdominal/vaginal approach is 16 of the 273 procedures Theorized mesh erosion as manifestation of bacterial contamination – consistent with finding higher erosion rates with vaginal placement	
Vaginal: bilat sacrospinous vault suspension Abdominal: colposacral suspension	2 U S	1989	Vaginal: permanent monofilament suture Abdominal: permanent monofilament suture	42 1:38	30 16	Vaginal: 33 Abdominal: 16	NR	Randomized comparison of vaginal and abdominal approach Dyspareunia Vaginal 15%, Abdominal 0%	

*Ref Line 2 Location: U:US; E:Europe Line3 Mesh Use: I:Interposition (Patch); S: Sling; B: Both; NM: No mesh

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Comparison of Meshes in the Pelvic Floor Repair Studies (from Lit Review)

Sample Description	Material Type	Fabric Const.	Yarn Const.	%Porosity	Thickness (mils)	Unit Weight (mg/cm2)	Burst Strength (psi)
Mersilene	Polyester	Knitted Mesh	Multi-Filament 30 denier	62.7	10.24	4.18	81.75
Prolene Mesh	Polypro-Pylene	Warp Knit	Mono-Filament 5-6mil	52.6	19.41	7.64	247.50
Prolene Soft Mesh	Polypro-Pylene	Warp Knit	Mono-Filament 3.5mil	Not Available	15.84	4.6	110.50
Vypro Mesh	50/50 Polypropylene/ 90/10 PGA/ PLA	Warp Knit	Multi-Filament for both	70.8	17.31	5.75	90.24
PTFE or e-PTFE	Polytetra-fluoro-ethyl	Extruded Film	Not Applicable	Not Applicable	Not Available	Not Avail.	Not Avail.
Mixed Fiber PGA/PET	PGA/ PET	Mesh	Multi-Filament	Not Available	Not Available	Not Avail.	Not Avail.

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